Food and Drug Administration Office of Regulatory Affairs
Summary Report
For Sample Number: 504299

TD Sample Number: **Import Sample Number**

This is an accurate reproduction of the original electronic record as of 01/04/2013

Sample Class: Normal Everyday Sample
Sample Flag:
Home District:

Sample Origin: Domestic
Sample Type: Official
Orig C/R and Records To: NWE-DO

Sample Basis: Other-Compl
Collecting District: NWE-DO
Collection PACs: 56R814

Product Name: Potassium Chloride (Replenisher); Human - Rx/Combination Ingredient; Large Volume Parenteral >=100ml

Product Description: Low K Cardioplegia solution

Collection Reason: Analyze for sterility. Brigham & Women's Hospital reported two patients with unusual disseminated Aspergillus fumigatus infection after receiving cardioplegia solution from New England Compounding Center.

Lab: SAN-LAB
Split Num: 0
Date Received: 10/16/2012
Date Out of Lab: 01/04/2013
District Conclusion:
District Conclusion Made By:
District

Disposition Reason:
Disposition Authorized By:
Disposition Authorized Date:

Performing Org	**PAC**	**LID**	**PAF**	**Compliance No**	**Lab Class-Description**	**Laboratory Status**
SAN-MICRO	56R814		MIC		3 - Adverse Findings	Completed

Lab Conclusion

Brevibacillus choshinensis found in Composite 3 (Sub 13-18)
No growth observed in Composite 1-2, 4.
Suitablility tests satisfactory.
Controls satisfactory.

DKL
Acting DD
2/5/2013

Lab Conclusion Date
01/04/2013

Lab Conclusion Made By
Lau,Henry K

Date: 01/04/2013

FLAG

ANALYST WORKSHEET	1. PRODUCT Cardioplegia		2.. SAMPLE NUMBER 504299
3. SEALS ☐ NONE ☒ INTACT ☐ BROKEN	4. DATE REC'D 10/16/12	5. RECEIVED FROM Jim Gilchrist	6. DISTRICT OF LABORATORY SAN-DO

7. DESCRIPTION OF SAMPLE

Three brown paper bags taped closed id'd as "Sample 504299 10/12/12 KC subs ** of 47 Bag * of 3" with Bag 1:sub 1-16, Bag 2:sub 17-32, Bag 3:sub 33-47 and officially sealed as "504299 10/12/12 Kent Conforti, CSO" containing 16, 16, 15 subs, respectively. Each sub id'd on a sticker as "Sample 504299 10/12/12 Sub * of 47" and numbered 1-47. Sample was received at room temperature and in good condition

8. NET CONTENTS	☐ NOT APPLICABLE ☒ NOT DETERMINED ____ UNITS EXAMINED	DECLARE/UNIT 265.5mL AMOUNT FOUND ____ % OF DECLARED ____	9. LABELING: 3 ORIGINAL(S) SUBMITTED ____ PHOTOCOPIES SUBMITTED ☐ NONE

10. SUMMARY OF ANALYSIS

Container:	A clear plastic bag 16.5cm by 25.5cm heat sealed closed containing one plastic pouch of product 19cm by 9 cm with two nozzles and stoppers each approx. 4cm long and 1cm wide.
Labeling:	A commercially blue printed on the pouch "250mL 0.9% SODIUM CHLORIDE// INJECTION, USP// HOSPIRA 2004" and address. Also a yellow sticker label with black prints "Cardioplegia-Low K (22mEg)", concentration of Sodium Chloride, Potassium Chloride, and Magnesium Sulfate. "Total Volume: 265.5mL", storage instruction, manufacturer.
Codes:	Blue printed code on the bag "LOT 16-802-KL" and black printed code on the yellow sticker as "Exp: 10/15/2012 Lot: 09242012@55" on all subs.
Product:	An opaque liquid.
Method:	USP, 35th ed./ NF 30, 2012, Ch.71 Sterility analysis by membrane filtration and suitability test.
Analysis:	For sterility, 23 subs examined as 4 composites of 6 and5 subs (Composite 1 = 1-6, Composite 2 = 7-12, and Composite 3 = 13-18, and Composite 4 = 19-23) each for microbial contamination then for suitability test.
Result:	Brevibacillus choshinensis found in Composite 3 (Sub 13-18). No growth observed in Composite 1 (Sub 1-6), Composite 2 (Sub 7-12), and Composite 4 (Sub 19-23). Suitability tests satisfactory. Controls satisfactory.

11. RESERVE SAMPLE

Sub 1-23 were used up in analysis and Sub 24-47 left intact id'd as in item #7 above and additionally id'd as "504299 10/16/12 HKL". The intact subs were returned to two original paper bags additionally id'd as "10/16/12 HKL" and official sealed as "504299 11/2/12 HENRY K. LAU, Analyst". Then tape closed and returned to sample custodian on 11/2 /12. The 2nd and 3rd original seals were left on the bags and additionally id'd as "10/16/12 HKL". The 1st official seal is attached to Attachment A.

12.a. ANALYST SIGNATURE (*Broke Seal* ☒) Henry Lau (For Sterility and Suitability)	Andrew Liu (received sample)	13. WORK-SHEET CHECK a. BY
b. Eileen Liu (For Sterility and Suitability)	Teresa Lee (For isolate confirmation)	b. DATE 2-1-13
c. Elaine Yeh (For isolate confirmation) Elaine Yeh	Jenny Yee (For isolate confirmation) Jenny K. Yee	14. DATE REPORTED 1-4-13

FORM FDA 431 (5/84) PREVIOUS EDITION IS OBSOLETE PAGE 1 OF 8 PAGES

ATTACHMENTS A-D

11/2/12
EL

GENERAL CONTINUATION SHEET	PRODUCT Cardioplegia	SAMPLE NO. 504299

Procedure:

Product was tested by membrane filtration. Product testing performed in a horizontal laminar flow hood certified in compliance with Class 100 conditions, located in a controlled environment clean room as described in Federal Standard No. 209E.

Prior to analysis, the product containers were decontaminated by 0.5% bleach and air-dried in the laminar flow hood. Product from five and six subs examined as one composite for sterility; four composites were analyzed.

Bags were disinfected with 70% alcohol at top (the hanging end). A pair of sterile scissors was used to make an opening at the hanging end. Approximately100mL of Fluid A was used to pre-wet the filter in the six-place manifold. Using a sterile pipette, entire content aseptically transferred into the filtration funnel from each of five/six subs, pooled, and filtered through one filtration unit of a six-place manifold. After the product was filtered, three 100 mL volumes of Fluid A were passed through the same filtration unit. The filter was halved using sterile scissor and forceps. One filter half aseptically placed into 100 mL of Fluid Thioglycollate (Thio) medium and the other half into 100 mL of Soybean Casein Digest (SCD) medium.. Fluid Thio was incubated at 33±2°C, SCD at 23±2°C for 14 days or until growth observed.

Media, environmental, system, and equipment controls run in parallel with the sterility test:

Two unopened vessels of each medium incubated in parallel with product test media, used as negative media control.

Two opened vessels of each medium, two opened SCD agar plates, and two opened PDA plates placed in working areas of the hood, and a second set of the above described opened media placed on the bench top during analysis. Rodac plates were used to test hood surface, bench surface, floor in the clean room. Contact plates were use for analyst's gloves and gown. Then one STA air sampling plate of the hood environment during testing, all incubation in parallel as environmental controls.

System control consisted of the furthest filtration unit from the vacuum source of the six-place manifold, through which three 100mL volumes of Fluid A passed. The filter was halved and halves incubated in media in parallel with product filter halves.

Sterile scissor and forceps dipped in SCD from the same sterilized lot were incubated in parallel as negative equipment controls.

PRODUCT Cardioplegia

SAMPLE NO. 504299

Primary Media: Fluid Thio/SCD

Sterility Daily Observation Record

Date Started: 10/17/12

Sub No.	Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7		Day 8		Day 9		Day 10		Day 11		Day 12		Day 13		Day 14		Final Results
C1: 1-6	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	NO growth
C2: 7-12	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	NO growth
C3: 13-18	-	-	-	-	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	growth
C4: 19-23	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	NO growth
Date	10/18/12		10/19/12		10/20/12		10/21/12		10/22/12		10/23/12		10/24/12		10/25/12		10/26/12		10/27/12		10/28/12		10/29/12		10/30/12		10/31/12		
Analyst	EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		

"+" = growth
"-" = no growth
"T" = sample-induced turbidity
"NC" = not checked

Fluid Thio incubated in Incubator # 1471 @ 33°± 2°C.
SCD incubated in Incubator # 142 @ 23°± 2°C.

H = Holiday, W= Weekend, L=Leave

Remarks:

ANALYST(S)

PAGE 3 OF 8 PAGES

MICRO STERILITY1, V1.0 (Effective Date 3/14/2005)

PRODUCT Cardioplegia

SAMPLE NO. 504299

Sterility Fluid Thio/SCD Control Daily Observation Record

Date Started: 10/17/12

10/18/12 10/19/12 10/20/12 10/21/12

Control		Day 1		Day 2		Day 3		Day 4		Day 5		Day 6		Day 7		Day 8		Day 9		Day 10		Day 11		Day 12		Day 13		Day 14		Final Results
Unopened media 2 each	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	Negative No growth
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Exposed media laminar hood, 2 each	L	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	R	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Exposed media, bench top, 2 each	L	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	R	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Scissors Dip, 2 each	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Forceps Dip, 2 each	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
	2	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Date		10/18/12		10/19/12		10/20/12		10/21/12		10/22/12		10/23/12		10/24/12		10/25/12		10/26/12		10/27/12		10/28/12		10/29/12		10/30/12		10/31/12		
Analyst		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		EL		

"+" = growth
"-" = no growth
"T" = sample-induced turbidity
"NC" = not checked

Fluid Thio incubated in Incubator # 1471 @ 33°± 2°C.
SCD incubated in Incubator # 142 @ 23°± 2°C.

H = Holiday, W= Weekend, L=Leave

Remarks:

ANALYST(S)

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MICRO STERILITY2, V1.0 (Effective Date 3/14/2005)

PRODUCT Cardioplegia

SAMPLE NO. 504 299

Sterility Agar Plate Control Daily Obeservation Record

Incubator @ 33±2° C 1471
Incubator @ 23±2° C 142
Date started: 10/17/12

= # of distinct colonies
"-" = No Growth
"T" = sample induced turbidity
"NC" = not checked

SCD agar incubated @23±2° C on days 1-3 and 33±2° C on days 4 and 5.
PDA plates incubated @23±2° C for days 1-5
RODAC plates incubated @33±2° C for days 1 and 2.

Negative Controls		10/18/12 Day 1	10/19/12 Day 2	10/20/12 Day 3	10/21/12 Day 4	Day 5	Final Results
Exposed SCD plates, hood	L	-	-	-	-	-	Negative, NO growth
	R	-	-	-	-	-	
Exposed SCD plates, benchtop	L	-	-	-	-	-	
	R	-	-	-	-	-	
Air Sampler (SCD agar)	1	-	-	-	-	-	
	2	~~10/18/12~~		~~EL~~			
Exposed PDA plates, hood	L	-	-	-	-	-	
	R	-	-	-	-	-	
Exposed PDA plates, benchtop	L	-	-	-	-	-	
	R	-	-	-	-	-	
RODAC plates, hood	L	-	-	-	-	-	
	R	-	-	-	-	-	
RODAC plates, floor	L	-	-	-	-	-	
	R	-	-	-	-	-	
	C	-	-	-	-	-	
RODAC plates, wall	L	-	-	-	-	-	
	R	-	-	-	-	-	
Analyst HKL gloves	L	-	-	-	-	-	
	R	-	-	-	-	-	
Analyst HKL arms and torso	A	-	-	-	-	-	
	T	-	-	-	-	-	
Analyst HKL head and thigh	H	-	-	-	-	-	
	T	-	-	-	-	-	
Analyst EL gloves	L	-	-	-	-	-	
	R	-	-	-	-	-	
Analyst EL arms and torso	A	-	-	-	-	-	
	T	-	+*	~~10/19/12~~		~~EL~~	Please see remarks below
Analyst EL head and thigh	H	-	-	-	-	-	Negative, NO growth
	T	-	-	-	-	-	
Positive Controls A. brasiliensis							
PDA inoculated with ~~Candida albicans~~ B. Subtilis 10/18/12 EL		+					Controls Satisfactory
SCD inoculated w/ ~~P. aeruginosa~~ B. Subtilis 10/18/12 EL		+					
RODAC inoculated w/ ~~P. aeruginosa~~ 10/18/12 EL		+					
Checking Date		10/18/12	10/19/12	10/20/12	10/21/12	10/22/12	
Analyst Initials		EL	EL	EL	EL	EL	

Remarks:
* 1 CFU found on 10/19/12 EL, id'd as Staphylococcus epidermidis, ~~seapage and attachment B & C~~ 10/25/12 EL

Analyst(s)

PRODUCT Cardioplegia

SAMPLE NO. 504299

10/29/12 EL

~~E. coli MPN~~ VITEK Record (VITEK Confirmation for ≤ 10 isolates)

Date Tested:

Sub No.	Dilution	Isolate[1]	VITEK Purity Check Saline[2]	VITEK Purity Check Organism[3]	[✓ VITEK] / API 20E Results	VITEK Attachment(s)	Summary
C3 (sub1378)	NA	TSB 3		P	Brevibacillus choshinensis	B	Brevibacillus choshinensis
B. subtilis ATCC 6633	NA	⊕ CTRL		P	B. subtilis	C-D	B. subtilis
~~E. coli ATCC 25922~~	10/29/12 EL						
Saline			NG				

[1] Isolate A, B or C from L-EMB plate streaked from positive EC tubes.
[2] G = Growth, NG = No Growth
[3] P = pure culture, M = mix culture, NG = No Growth

ANALYST(S)

PAGE 6 OF 8 PAGES

MICRO WS 4.12, V1.0 (Effective Date 01/12/10)

GENERAL CONTINUATION SHEET	PRODUCT Cardioplegia	SAMPLE NO. 504299

BACTERIOSTASIS AND FUNGISTASIS

Date Started : 10/31/12

1. Procedure: less than 100 cells/spores each of test organisms 1, 2, 3, 5, & 6 were added to bottles containing 100 mL of Fluid Thioglycollate medium and 265.5 x16 [✓ mL]/gm product sample; less than 100 cells/spores each of test organisms 1, 2, 3, 4, & 5 were added to bottles containing 100 mL of Soybean Casein Digest medium and 265.5 x16 [✓ mL]/gm product sample. Both sets of media product were then incubated as in product sterility analysis. Similar sets of media without product were also inoculated as above and incubated with test bottles.

2. Modification: NONE

3. Results: Suitability tests satisfactory

Test Organisms	Media With Product		Media Without Product	
	Thio. 33°C	SCD 23°C	Thio. 33°C	SCD 23°C
1. *Pseudomonas aeruginosa* ATCC# NA	NA →			→
2. *Bacillus subtilis* ATCC# 6633 Lot 043889, exp 2012/11/30	G	G	G	G
3. *Staphylococcus aureus* ATCC# NA	NA →			→
4. *Aspergillus* ~~*niger*~~ 10/31/12 EL brasiliensis ATCC# 16404 Lot 160336, exp 2013/08/31		G		G
5. *Candida albicans* ATCC# NA	NA →			→
6. *Clostridium sporogenes* ATCC# NA	NA		NA	

ANALYST(S)

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FORM FDA 431a (SAN-DO MICRO STERILITY4, V1.0) Effective Date 3/14/2005

PRODUCT	SAMPLE NO.
Cardioplegia	504299

Sterility QA Record

Media	Vol/ Unit	Autoclave No. or [✓ Lot No.]	Reagent	Autoclave No. or [✓ Lot No.]
Fluid Thioglycollate	100 mL	5112	Vitek GNI Cards	
Soybean Casein Digest	100 mL	5101	Vitek GP Cards	98163559
Diluting Fluid A	100 mL	5113	BAP	98184337
Diluting Fluid D	100 mL		Saline	98136269
Rodac Plates	12 mL	5128/5131		
SCD Plates	20 mL	5096	ATCC 25923, S. aureus	160, T4
SCD Slants	5 mL		ATCC 6633 B. subtilis	043889
PDA w/40 ppm chlortet	20 mL	5098	ATCC 16404 A. brasiliensis	160336
MacConkey Plates	20 mL		0.2 µm filter	R2HA 29402
Air sampler plate	80 mL	5096		

Equipment	Autoclave No. or [✓ Lot No.]
6-Place Manifold with 0.45 µm filter and 0.22 µm bleed filter	5121
3-Place Manifold with 0.45 µm filter and 0.22 µm bleed filter	
13 mm Swinney Unit with 0.22 µm filter and 20 Gauge needle	
3 cc syringes	
Air Sampler Probe	5181
Carboy	5181
Forceps	4666
Gown Sets	5181
Mop head	5181
Paper towels	5181
Scissors	5106
Vitek	1244

Analyst(s)
Elaine Yeh Jenny K. Yee

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MICRO STERILITY10, V1.0 (Effective Date 3/14/2005)

Attachment A

504299
10/16/12
EL

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
New England District Office

SAMPLE NO.
SIGNAT

504299
DATE 10/12/12
URE
RINTED NAME & TITLE (Investigator, Inspector, Analyst, etc.)
Kent Conforti CSO

SEAL BROKEN BY
DATE 10/16/12

FDA 415a (4/07)

Attachment B

504299
10/29/12
TL

U.S. FDA - San Fransisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Oct 29, 2012 01:33 PDT
Autoprint

Isolate Group: 504299 TSB3-1 504299 TSB 3

Bionumber: 4723101000010000
Selected Organism: Brevibacillus choshinensis

Comments:	

Identification Information	**Card:** BCL	**Lot Number:**	239242810	**Expires:**	Aug 7, 2013 13:00 PDT	
	Completed: Oct 29, 2012 02:00 PDT	**Status:**	Final	**Analysis Time:**	14.25 hours	
Selected Organism	97% Probability	**Brevibacillus choshinensis**				
	Bionumber: 4723101000010000			**Confidence:**	Excellent identification	
SRF Organism						

Analysis Organisms and Tests to Separate:

Analysis Messages:

Contraindicating Typical Biopattern(s)
Brevibacillus choshinensis AGLU(12),GlyA(76),

Biochemical Details

1	BXYL	-	3	LysA	-	4	AspA	+	5	LeuA	+	7	PheA	+	8	ProA	+
9	BGAL	-	10	PyrA	+	11	AGAL	-	12	AlaA	+	13	TyrA	+	14	BNAG	-
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	-
25	ELLM	+	26	MdX	-	27	AMAN	(-)	29	MTE	-	30	GlyA	-	31	dMAN	-
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	-	39	IRHA	-	41	BGLU	-
43	BMAN	-	44	PHC	-	45	PVATE	-	46	AGLU	+	47	dTAG	-	48	dTRE	-
50	INU	-	53	dGLU	-	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	-	59	KAN	-
60	OLD	-	61	ESC	-	62	TTZ	-	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment C

504299
10/29/12
TL

U.S. FDA - San Fransisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Oct 29, 2012 12:57 PDT
Printed by: labtech

Isolate Group: B. subtilis-1 B. subtilis

Bionumber: 3373141605443260
Selected Organism: Bacillus subtilis

Comments:	

Identification Information	**Card:** BCL		**Lot Number:**	239242810	**Expires:**	Aug 7, 2013 13:00 PDT
	Completed:	Oct 29, 2012 01:59 PDT	**Status:**	Final	**Analysis Time:**	14.25 hours
Selected Organism	88% Probability		**Bacillus subtilis**			
	Bionumber:	3373141605443260			**Confidence:**	Low discrimination
SRF Organism						

Analysis Organisms and Tests to Separate:	
Low Discrimination Organism	
Bacillus subtilis/amyloliquefaciens/atrophaeus	
Bacillus amyloliquefaciens	dARABINOSE(10),lRHAMNOSE(10),
Bacillus atrophaeus	lRHAMNOSE(50),OX(0),
Bacillus subtilis	dARABINOSE(10),lRHAMNOSE(10),OX(50),
Bacillus vallismortis	dARABINOSE(90),lRHAMNOSE(90),OX(100),

Analysis Messages:

See product information for additional information.

Contraindicating Typical Biopattern(s)	
Bacillus subtilis/amyloliquefaciens/atrophaeus	dMNE(88),APPA(17),GLYG(69),LysA(3),BGAL(25),INU(25),AGLU(94),
Bacillus vallismortis	dRIB(90),dMNE(99),APPA(5),LysA(25),dTRE(25),

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Attachment D

504299
10/29/12
TL

U.S. FDA - San Fransisco District

bioMerieux Customer: 03268
System #: C23156

Laboratory Report

Printed Oct 29, 2012 12:57 PDT
Printed by: labtech

Isolate Group: B. subtilis-1 B. subtilis

Bionumber: 3373141605443260
Selected Organism: Bacillus subtilis

Biochemical Details

1	BXYL	+	3	LysA	+	4	AspA	-	5	LeuA	+	7	PheA	+	8	ProA	-
9	BGAL	+	10	PyrA	+	11	AGAL	+	12	AlaA	+	13	TyrA	+	14	BNAG	(-)
15	APPA	+	18	CDEX	-	19	dGAL	-	21	GLYG	-	22	INO	-	24	MdG	+
25	ELLM	+	26	MdX	-	27	AMAN	-	29	MTE	-	30	GlyA	+	31	dMAN	+
32	dMNE	-	34	dMLZ	-	36	NAG	-	37	PLE	+	39	IRHA	-	41	BGLU	+
43	BMAN	-	44	PHC	-	45	PVATE	+	46	AGLU	-	47	dTAG	-	48	dTRE	+
50	INU	+	53	dGLU	(+)	54	dRIB	-	56	PSCNa	-	58	NaCl 6.5%	+	59	KAN	-
60	OLD	-	61	ESC	+	62	TTZ	+	63	POLYB_R	-						

Installed VITEK 2 Systems Version: 05.01
MIC Interpretation Guideline:
AES Parameter Set Name:

Therapeutic Interpretation Guideline:
AES Parameter Last Modified:

Food and Drug Administration Office of Regulatory Af

Collection Report

For Sample Number: 504299

This is an accurate reproduction of the original electronic record as of 10/15/2012

Micro
MIC
504299 56R814

Flag		Flag Remarks			

Episode Number	Origin	Basis	Sample Type	FIS Smpl Num	Status
	Domestic	Other-Compln	Official	13206539	In Progress
FEI	**Date Collected**	**Product Code**	**Responsible Firm**	**PAC**	**Hours**
3003623877	10/12/2012	65RDN14	Manufacturer	56R814	
Compliance Num	**Country of Origin**				
Related Smpl Num	**Position Class**	**Sampling District**	**NDC Number**	**Permit Number**	**Storage Rqrmnt.**
	INV	NWE-DO			
Dealer is Consumer	**Crx/DEA Schedule**	**Recall Num**	**Consumer Compl. Num**	**Brand Name**	
No				New England Compounding Center Low K Cardioplegia	

Product Description
Cardioplegia

Product Label

Reason for Collection	MFG Codes	Expiration Date
Analyze for sterility. Brigham & Women's Hospital reported two patients with unusual disseminated Aspergillus fumigatus infection after receiving cardioplegia solution from New England Compounding Center.		

Firm Legal Name	Address	Type of Firm	Firm FEI	FCE
Brigham And Womens Hospital	75 Francis St Boston, MA 02115-6110 US	Dealer	1270016	
New England Compounding Center	697 Waverly St Framingham, MA 01702-8589 US	Manufacturer	3003623877	

Size of Lot	Est. Value	Rcpt Type	Carrier Name	Date Shipped
47 units x 265.5 mL				

Date 10/16/12
No. of Pkg. 3
Pkg. Type BAGS
Location 1452-49B
Initials:
☐ Repacked by Sample Custodian

Description of Sample

Method of Collection

How Prepared

Collector's Identification on Package and/or Label

Collector's Identification on Seal

Sample Delivered To	Date Delivered	Orig C/R & Records To
	10/15/2012	NWE-DO
	Lab w/Split Sample	**Lab**
	0	SAN-LAB

Document Number	Document Date	Document Type	Document Remarks

Remarks

ANALYSES

✓ Microbiology ___ Seafood Filth
___ Decomposition ___ Metals
___ Chemistry ___ Other ___

Food and Drug Administration Office of Regulatory Affairs

Collection Report

For Sample Number: 504299

This is an accurate reproduction of the original electronic record as of 10/15/2012

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
		No	Yes	Kent A Conforti

Name of Signer	Date & Time of Signature	Meaning
	ET	

Date: 10/15/2012

1. TO: U.S. FOOD AND DRUG ADMINISTRATION
CITY: San Francisco STATE: CA SYMBOL: SAN-DO

2. DATE 10/15/12

3. FROM: *(District, Division or Unit and Symbol)*
NWE-DO

4. SAMPLE NUMBER 504299 & 504300

5. FIRM NAME
New England Compounding Center

6. PRODUCT
Cardioplegia

7. FIRM ADDRESS *(Include Zip Code)*

8. REASON FOR COLLECTION *(Copy from C/R)*

9. ANALYSIS DESIRED
sterility

10. REMARKS
Products included in recall from NECC. Report from Brigham & Women's Hospital on ~~possible~~ - infection of 2 patients w/ Aspergillus fumigatus; possibly due to Cardioplegia use

Package 1 of 1 Packages

11. STORAGE INSTRUCTIONS
☐ REFRIGERATE AT ______ °F
☐ KEEP FROZEN
☒ KEEP AT ROOM TEMP
☐ OTHER *(Specify in remarks)*

12. INSPECTOR-INVESTIGATOR
Kent Contorti

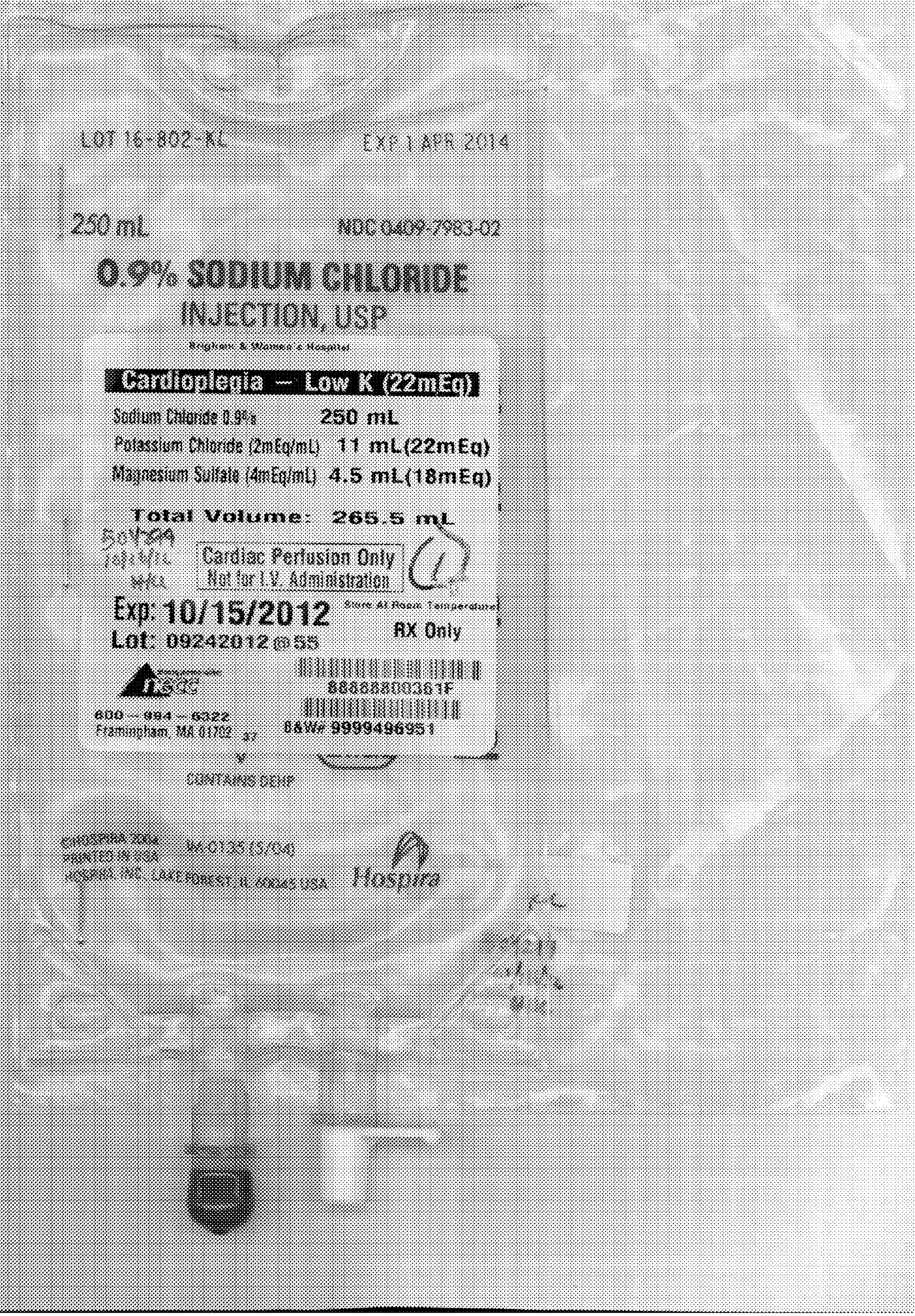
FORM FDA 525 (4/06) PREVIOUS EDITION MAY BE USED **SAMPLE PACKAGE IDENTIFICATION**

INSTRUCTIONS

1. Fill out all blocks completely and accurately following the instructions/precautions given in IOM section 4.5.5 and firmly glue flap closed.
2. If this envelope is used as a sample package for small items, place Form 415a "Seal" across flap and face of this form and attach another 525 "back-to-back" for any paperwork related to the sample.

labeling

504294
10/16/12
HMC



LOT 16-802-KL EXP 1 APR 2014

250 mL NDC 0409-7983-02

0.9% SODIUM CHLORIDE
INJECTION, USP

Brigham & Women's Hospital

Cardioplegia — Low K (22mEq)

Sodium Chloride 0.9%	**250 mL**
Potassium Chloride (2mEq/mL)	**11 mL(22mEq)**
Magnesium Sulfate (4mEq/mL)	**4.5 mL(18mEq)**

Total Volume: 265.5 mL

504294
10/16/12
HMC

Cardiac Perfusion Only
Not for I.V. Administration

Store At Room Temperature

Exp: 10/15/2012
Lot: 09242012@55

RX Only

88888800361F

800 – 994 – 6322
Framingham, MA 01702 37

B&W# 9999496951

CONTAINS DEHP

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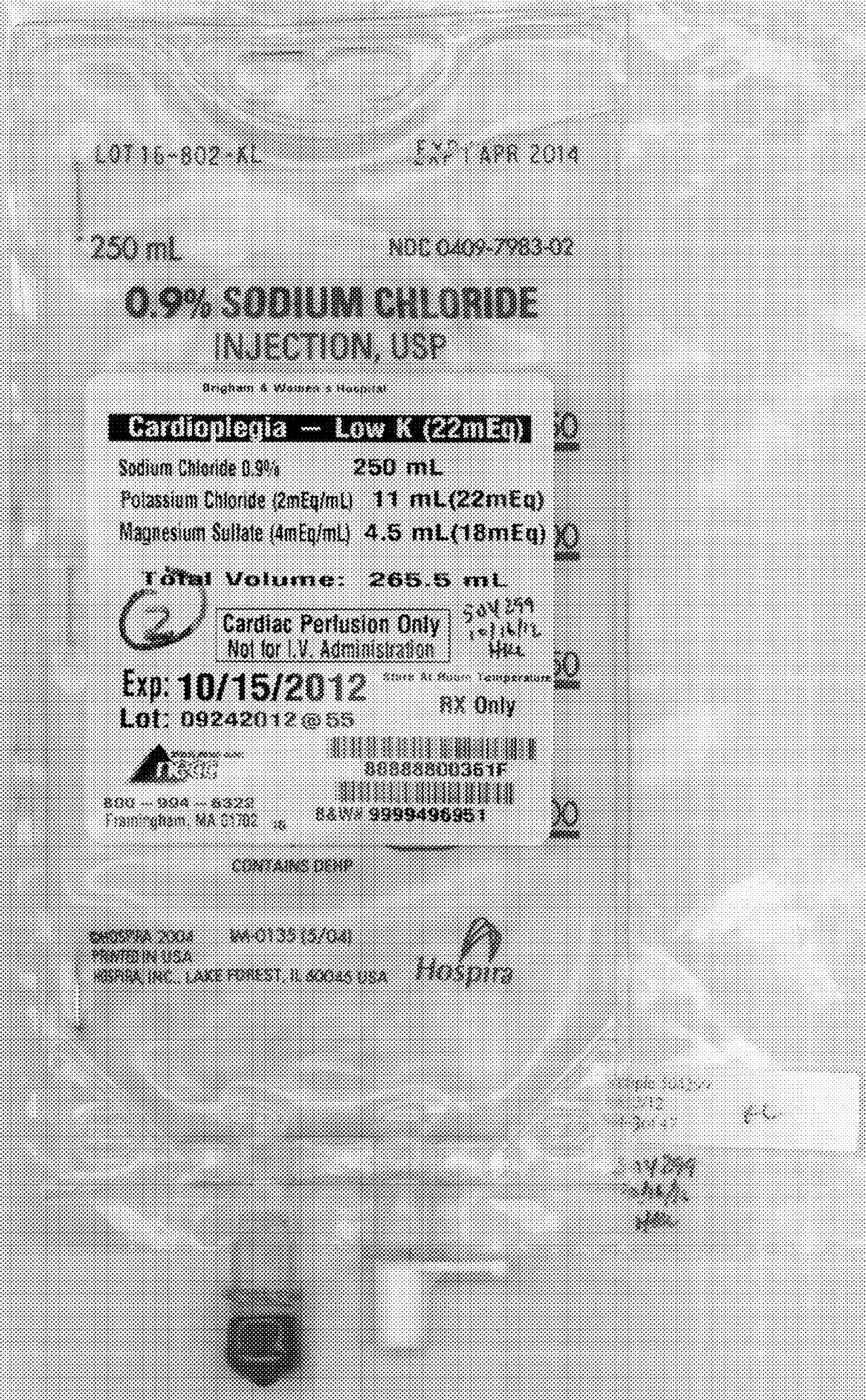
Labeling

504299
10/16/12
HKL



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2

Cardiac Perfusion Only
Not for I.V. Administration

504299
10/16/12
HKL

Exp: 10/15/2012

Store At Room Temperature

Lot: 09242012@55

RX Only

8888800361F

800 — 994 — 8323
Framingham, MA 01702

B&W# 9999496951

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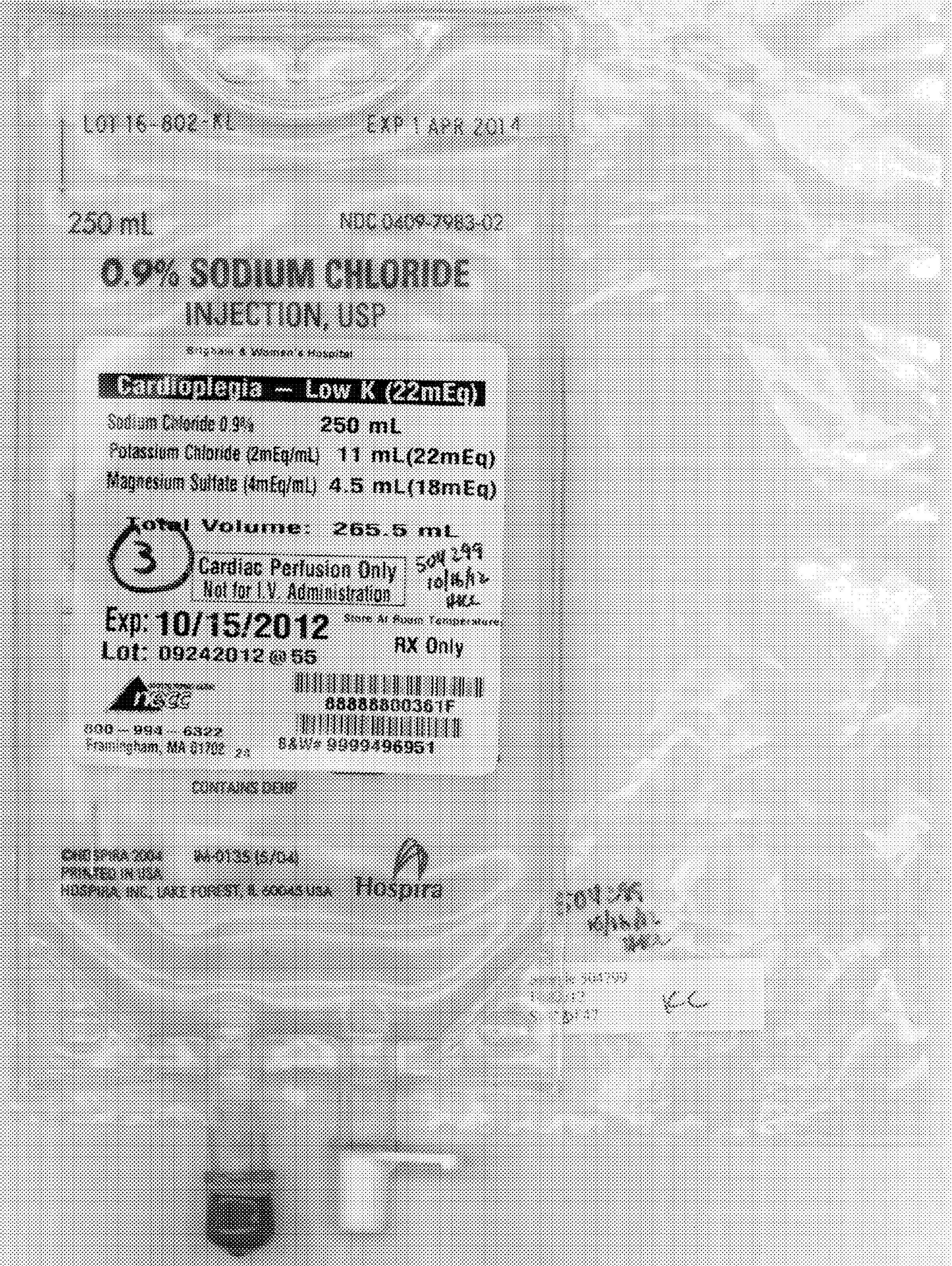
Labeling

504299
10/18/12
HRC



LOT 16-802-KL EXP 1 APR 2014

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3

Cardiac Perfusion Only
Not for I.V. Administration

504299
10/18/12
HRC

Exp: 10/15/2012
Store At Room Temperature
Lot: 09242012@55
RX Only

8888880361F

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B&W# 9999496951

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504299
10/18/12
HRC

Sample # 504299
KC